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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,043	03/17/2008	**David Gaudout**	102882-102	9257

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WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER	
PIHONAK, SARAH	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
08/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,043	GAUDOUT ET AL.	
	Examiner	Art Unit	
	SARAH PIHONAK	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6 and 11-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6,11-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application, filed on 3/17/2008, is a national stage entry of PCT/FR04/03173, filed on 12/9/2004.

Priority

This application claims foreign priority to Application No. 0314394, filed on 12/9/2003.

Response to Remarks

1. Applicant's arguments filed 5/17/2010 have been fully considered but they are not persuasive. The Applicants have argued that O'Gara et. al. does not render the claims obvious, as O'Gara et. al. does not teach a garlic extract composition in which DAS3 is present in a greater amount than DAS2; however, this limitation was not present in the previous set of claims, on which the rejection had been based upon. In the response filed on 5/17/2010, claim 4 has been amended to recite the specific limitation that the amount of DAS3 present is greater than DAS2; new claims 20-21, which are dependent upon claims 11 and 12, also recite this limitation. In view of the claim amendments, modified rejections under 35 USC 103(a) have been made, which will be discussed in detail below.

The Applicants have also asserted that the presumption that components which are naturally present in garlic would also have been expected to be present in extracts of garlic produced during different processes is incorrect. The Applicants have argued that, under certain conditions, components of garlic such as Gluacs may decompose or decrease in concentration. The examiner has fully considered this argument; however,

without evidence to show otherwise, and as neither O'Gara et. al., Yu et. al., Block et. al., Lawson et. al., and Yeh et. al. explicitly teach that components such as Gluacs are not present in garlic extracts, it would have been expected that such naturally present components would have been present in the garlic extracts, without support to the contrary or in the absence of unexpected results. The examiner will consider comparison data for the garlic extract composition prepared by the prior art and the method used to prepare the instantly claimed composition. Due to the claim amendments, a modified rejection under 35 USC 103(a) has been made. Accordingly, this action is made FINAL.

The claims have been amended to remove the term "predominant" from claims 15 and 16; due to this amendment, the rejection under 35 USC 112, second paragraph is withdrawn.

2. Claims 4-6, and 11-21 are pending.

3. Claims 4-6, and 11-21 were examined.

4. Claims 4-6, and 11-21 are rejected.

Claim Rejections-35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et. al., *J. Agric. Food Chem.*, **37**, pp. 725-730, (1989), in view of O'Gara et. al., *Applied & Environmental Microbiology*, **66 (5)**, pp. 2269-2273, (2000), in view of Hsu et. al. EP Patent Application No. 945066 (all of previous record).

The claims are directed to a composition comprised of a biopesticide comprising diallyl sulfide (DAS), diallyl disulfide (DAS2), diallyl trisulfide (DAS3), and diallyl

tetrasulfide (DAS4), the sum by weight being at least one mg. per g. of composition, and formulation adjuvants, wherein DAS3 is present in a larger amount than DAS2.

Yu et. al. teaches a composition comprised of garlic extract, prepared by blending garlic cloves followed by distillation and extraction steps (p. 726, right column, last paragraph-p. 727, left column, top paragraph). Yu et. al. teaches that components of the garlic extract include DAS, DAS2, and DAS3, and that the amount of DAS3 present is greater than DAS2 (p. 728, Table II, 1.01083 mg of DAS3 and .54811 mg. of DAS2). The amount of DAS, DAS2, and DAS3 is at least 1 mg. per g. of garlic volatiles (DAS=.02960 mg.; DAS2=.54811 mg.; DAS3=.101083 mg.; total amount of the compounds such as allyl propyl polysulfides, particularly propyl allyl disulfide, present in garlic and garlic extracts = 2065.25 mg.) (Abstract; p. 729, Table II). DAS3 and DAS2 together = .6492 mg., which comprises at least 50% of the diallyl polysulfides present (DAS + DAS2 + DAS3=0.6788 mg.).

Yu et. al. does not teach that the composition comprises formulation adjuvants. It is not explicitly taught that diallyl tetrasulfide (DAS4) is present.

O'Gara et. al. teaches that garlic oil prepared by heating crushed garlic cloves followed by distillation, comprises DAS4 (p. 2269, right column, first full paragraph; p. 2270, right column, Table 1).

O'Gara et. al. teaches that garlic oil prepared by the heating of crushed garlic followed by distillation processes comprises DAS4. Therefore, as it is taught that DAS4 is naturally present in garlic, it would have been expected that the garlic composition taught by Yu et. al. would also have been comprised of DAS4.

O'Gara et. al. does not explicitly teach formulation adjuvants for biopesticide compositions, such as plant oils adjuvants.

Hsu et. al. teaches a natural pesticide composition comprised of extracts of garlic and adjuvants, such as essential oils, including cottonseed oil, cinnamon oil, along with other plant oils (Abstract; p. 2, paragraph [0005]). Hsu et. al. teaches that garlic extract includes garlic oil (p. 2, paragraph [0007]). Hsu et. al. teaches that the pesticide comprised of the garlic extract and essential oils is effective against fungal infestations of plants and also possesses anti-bacterial properties (p. 2, paragraph [0003]). Additionally, Hsu et. al. also teaches that the composition comprised of the garlic extract and plant oils was diluted with water, which in some instances resulted in reduced effectiveness of the formulation as a pesticide (p. 4, paragraphs [0023-0024]).

It would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to add an adjuvant such as cottonseed oil, cinnamon oil, or another plant oil to the garlic extract composition taught by Yu et. al., because Hsu et. al. teaches that a composition comprised of garlic extracts (including garlic oil) and essential oils is an effective pesticide and bactericide. As the garlic composition taught by Yu et. al. is comprised of an extract of garlic, and comprises DAS, DAS2, DAS3, and DAS4 at a weight of at least one mg. per gram of composition, it would have been obvious to one of ordinary skill in the art to add formulation adjuvants to the composition such as those taught by Hsu et. al., for the purpose of creating a biopesticide.

Claim Rejections-35 USC § 103

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et. al., *J. Agric. Food Chem.*, **37**, pp. 725-730, (1989), in view of O'Gara et. al., *Applied & Environmental Microbiology*, **66 (5)**, pp. 2269-2273, (2000), and in view of Hsu et. al. EP Patent Application No. 945066, as applied to claims 4-6 above, and further in view of Lawson et. al., *J. Natural Products*, **54 (2)**, pp. 436-444, (1991), and Yeh et. al., *The Journal of Nutrition*, **131 (3S)**, pp. S989-S993, (2001), and Block et. al., *Pure & Applied Chem.*, **65 (4)**, pp. 625-632, (1993) (all of previous record).

12. The claims are directed to a composition containing DAS, DAS2, DAS3, DAS4, at a sum by weight of at least one mg./g. composition, and gamma-glutamayl-S-allyscysteine (Gluacs). Atleast 50% of the diallyl polysulfides consists of diallyl disulfide and diallyl trisulfide. The composition comprises an extract of garlic, and contains diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, allicin, and allicin. The compounds diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, and allicin are predominant in the extract of garlic, and the diallyl polysulfides represent more than 50 % of the sulfur-containing compounds of the garlic extract. The claims are also directed to a composition in which DAS3 is present in a greater amount than DAS2.

The teachings of Yu et. al., O'Gara et. al., and Hsu et. al. are discussed supra. Yu et. al. further teaches that allyl propyl polysulfides, such as propyl allyl disulfide, are present in garlic and garlic extracts (Abstract; p. 728, Table II). It is taught that methyl propyl polysulfide, such as methyl propyl disulfide, is present in garlic extracts (p. 729, Table II). Yu et. al. teaches that the garlic extract is obtained by homogenizing the garlic cloves, followed by extraction and distillation (p. 726, right column, lower paragraph-p. 727, left column, top paragraph). This process is consistent with the claimed process of milling the garlic under hot conditions, and recovering the volatile fractions. Steps such as filtering the garlic and concentrating the distillate under vacuum would have been considered part of the distillation process to one of ordinary skill in the art. O'Gara et. al.

teaches that garlic oil comprises methyl allyl polysulfides, such as methyl allyl disulfide, methyl allyl trisulfide, methyl allyl tetrasulfide, methyl allyl pentasulfide, and methyl allyl hexasulfide (p. 2270, right column, Table 1). O'Gara et. al. also teaches that garlic oil further comprises dimethyl polysulfides, such as dimethyl tri-, tetra-, and pentasulfide (p. 2270, right column, Table 1), and that the compound, allicin, is formed by a catalytic process when garlic cloves are crushed (p. 2269, left column, last paragraph-right column, top paragraph). It is also taught that during the process of preparing garlic oil, or when crushed garlic cloves are heated and processed by distillation, allicin becomes converted to diallyl sulfides, diallyl polysulfides, and many other sulfide compounds observed in garlic oil and garlic extracts (p. 2269, right column, first full paragraph). O'Gara et. al. also teaches that the compound alliin is present in garlic, and during crushing of garlic cloves alliin reacts with the enzyme alliinase to form allicin (p. 2269, left column, last paragraph-right column, top paragraph). Thus, as the composition prepared by Yu et. al. and Hsu et. al. are also comprised of garlic extracts, it would have been expected that this composition would also have comprised dimethyl polysulfides, such as dimethyl tri-, tetra-, and pentasulfide, allicin, alliin, as these compounds are naturally present in garlic, or as in the case of allicin, form when garlic cloves are crushed.

Yu et. al., O'Gara et. al., and Hsu et. al. do not explicitly teach that garlic extract contains gamma-glutamyl-S-allylcysteine, dipropyl polysulfides, or dimethyl polysulfinate.

Lawson et. al. teaches that the compound gamma-glutamyl-S-allylcysteine is present in garlic extracts (Abstract; p. 436, first paragraph). Lawson et. al. teaches that this compound is observed in extracts prepared from homogenized garlic (p. 442, Table 1; p. 443, second full paragraph).

Yeh et. al. teaches that dipropyl polysulfides such as dipropyl disulfide and dipropyl trisulfide are naturally found in garlic, and contribute to the medicinal properties of garlic (Abstract; p. S992, left column, middle paragraph).

Block et. al. teaches that extracts of garlic naturally contain dimethyl thiosulfinate, among other thiosulfinate and sulfide containing compounds (Abstract; p. 630, Table I, 13th entry). Block et. al. teaches preparing the garlic extract by homogenizing garlic cloves, followed by vacuum distillation to recover the concentrated extracts (p. 628, lower paragraph-p. 629, top paragraph).

Collectively, Yu et. al., O'Gara et. al., Yeh et. al., Lawson et. al., Block et. al., teach that diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, allicin, alliin, and gamma-glutamyl-S-allylcysteine are all naturally found in garlic, as they have been identified in garlic extracts; therefore, it would have been obvious to one of ordinary skill in the art that these components would have been present in the garlic extract composition taught by Yu et. al., in which the amount of DAS3 is greater than DAS2. Yu et. al. also explicitly teaches that diallyl disulfide and diallyl trisulfide constitute more than 50 % of the diallyl polysulfide compounds observed in garlic extracts, and the diallyl polysulfides represent more than 50 % of the sulfur-containing

compounds found in garlic extracts. Hsu et. al. teaches that a composition comprised of garlic extracts and plant oil adjuvants is a superior pesticide and biocide. Therefore, it would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to add a plant oil adjuvant to the garlic extract composition taught by Yu et. al., for formulation purposes, because it is known in the art that compositions comprised of garlic extracts (including garlic oil) are potent pesticides and biocides. Additionally, the prior art teaches that diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, allicin, alliin, and gamma-glutamyl-S-allylcysteine are all naturally found in garlic extracts; therefore, these compounds would also have been present in a composition comprised of garlic extracts.

13. Applicant's amendment necessitated the modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

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